POLICY AND COMMUNICATIONS BULLETIN
THE CLINICAL CENTER

Medical Administrative Series

M88-3 (rev.) 18 October 2000

MANUAL TRANSMITTAL SHEET

SUBJECT: Occurrence Reports

1. Explanation of Material Transmitted: This revised issuance describes the new web-based occurrence reporting system and use of form NIH-2458, "Report of Incident or Potentially Hazardous Situation." The policy was approved by the Medical Executive Committee at its meeting on 17 October 2000.

2. Material Superseded: MAS No. M88-3, dated 3 October 1988

3. Filing Instructions: "Other" Section

   Remove: No. M88-3, dated 3 October 1988

   Insert: No. M88-3 (rev.), dated 18 October 2000

DISTRIBUTION

Physicians, Dentists and Other Practitioners Participating in Patient Care

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SUBJECT: Occurrence Reports

PURPOSE

The identification and characterization of exceptional events related to patient care, protocol implementation, and service delivery are critical components of a comprehensive clinical quality improvement program. The Clinical Center Occurrence Reporting System (ORS) provides a confidential, non-punitive mechanism to collect and communicate information regarding such occurrences. The Clinical Center ORS will assist CC staff to:

1) identify clinical and operational opportunities for improvement;
2) identify adverse sentinel events;
3) identify instances of exceptional patient care and service delivery;
4) collect epidemiologic data regarding occurrences;
5) establish a database for analysis and tracking of occurrences;
6) provide data to drive performance improvement activities;
7) identify reportable events for reporting under the Safe Medical Devices Act.

The purpose of this issuance is to provide organizational guidance regarding policy and procedure for reporting occurrences and for managing and disseminating information about ORS data.

DEFINITIONS

Occurrence: Any event identified as exceptional by practitioners and staff. This includes, but is not limited to, events:

1) not consistent with routine safe operations and practices of the hospital;
2) not a natural or expected consequence of a patient's disease process or clinical research protocol;
3) that are considered "near misses" but pose a potential for adverse outcomes
4) that result in exceptional quality of patient care or service delivery;

Sentinel Event: An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof, requiring immediate attention and investigation.

POLICY AND PROCEDURE

Reporting and Documentation:

All occurrences related to patients, staff, visitors, environment, and equipment will be entered into the web-based Occurrence Reporting System (ORS) by staff trained and competent in the use of the ORS (see Training below). Occurrences will be entered into the ORS within 24 hours of the event. If the ORS system is not available due to technical problems or if a person wishing to report an occurrence does not have access to the system, a form NIH-2458, "Report of Incident or Potentially Hazardous Situation" (available through the Office of the Deputy Director for Clinical Care) should be completed and forwarded to the Deputy Director for Clinical Care within 24 hours of the occurrence.

Occurrences involving visitors and employees should be reported to the ORS even if the injured person refuses care or, in the case of an employee, is referred to the Occupational Medical Service.

If the occurrence is determined to be a sentinel event, the responsible practitioner will follow reporting procedures outlined in the Sentinel Event Policy (MAS No. M00-2).

Departmental and/or Institute staff identified by the Office of the Deputy Director for Clinical Care as having peer review and quality improvement responsibilities will be notified of all occurrences involving their programs/ departments. (The Office of the DDCC will maintain a current list of those individuals sanctioned under peer review to have access to the ORS data.)

Information collected using the ORS or NIH 2458 is not entered into the medical record; therefore the patient's practitioner is responsible for documenting an adverse occurrence in the patient's medical record, as appropriate. The patient and his/her significant other(s) should be notified about the occurrence.

Coordination and Dissemination of ORS Data

The Office of the Deputy Director for Clinical Care (DDCC) is responsible for coordinating, analyzing, and disseminating of ORS. Occurrences will be forwarded electronically (at the time of entry into the ORS) to appropriate Clinical Center and Institute clinical and operational staff for follow-up investigation. The Office of the DDCC will determine final disposition of each occurrence (e.g., issue resolved, issue requires organizational action).

Aggregate data regarding occurrences will be reported to the Clinical Quality Committee at least quarterly. Aggregate data will be provided to Clinical Center departments and Institute programs in formats and intervals determined by each department or Institute.

Training

All patient care practitioners and staff will be trained and demonstrate competence in the use of the ORS. Non-patient care staff will have access to the ORS through his/her Clinical Center Department Head or Institute Clinical Director. ORS training will be coordinated by the Office of the DDCC.

Peer Review

All occurrence reports are considered to be a part of the formal Clinical Center peer review process. The Office of the DDCC will maintain a list of active Clinical Center and Institute staff deemed part of the peer review process. These individuals will have access to the ORS database and may use these data for peer review, quality improvement, and educational activities.

Printing or distribution of hard copies of individual occurrence reports or of summary documents that contain occurrence-specific information is ***strictly limited*** to instances when the documents will facilitate formal discussions at peer review or clinical quality meetings. If hard copies are used for this purpose, the copies will be numbered for tracking purposes, collected at the end of each peer review/clinical quality meeting, and destroyed after the meeting.